

## QuickVue Flex Strep A Test

\*\*\*See package insert for more information\*\*\*

### Quality Control:

#### Built-in Control Features:

The QuickVue Flex Strep A Test contains built-in control features. The manufacturer's recommendation for daily quality control is to document these controls for EACH sample run. A control of the extraction procedure is provided by a color change from clear to **green** as the Extraction reagents are mixed. This indicates that the extraction procedure was performed correctly and proper reagent integrity. The appearance of a **blue** Control Line next to the letter "C" ensures that functional activity of the detection components is maintained, that the kit has been stored properly, and that the Test Cassette was assembled properly. If the Control Line does not develop within **5** minutes, the test result is **invalid**. A negative background control is provided by the clearing of background color in the Result Window and indicates that there were no immunological interfering substances in the specimen. It should be white to light pink within 5 minutes and not interfere with the reading of the test result.

#### Positive and Negative Quality Control:

Positive and Negative Control swabs are supplied in the kit. The Positive Control Swab is stored in the pink-capped tube; the Negative Control Swab is stored in the blue-capped tube. To test using these Control Swabs, place 4 drops of Extraction Reagent A and 4 drops of Extraction Reagent B into a clean tube. Remove the Control Swab from its container and add it to the tube. Hold the bottom of the tube so the swab head is slightly compressed. Rotate the swab 3 times. Wait one minute. Continue with the assay as instructed in Step 3 of the **Before Testing** Section.

### Before Testing:

1. For each patient specimen to be tested, place **4 drops** of Extraction Reagent A and **4 drops** of Extraction Reagent B into a clean tube. The solution should turn **green** when Extraction Reagent B is added.
2. Immediately add the throat swab specimen to the tube containing the green extraction solution. Hold the bottom of the tube so the swab head is slightly compressed. Rotate the swab 3 times.
3. Express **all** liquid from the swab head in the tube by rolling the swab against the inside of the tube and squeezing firmly as it is withdrawn. Discard the swab.
4. Put a clean tip in the tube.

### Perform Assay:

1. Remove Test Cassette from foil pouch and place on a clean, dry, level surface.
2. Add **2 drops** from the tube to the round sample well on the Test Cassette.
3. Begin timing – the Test Cassette should not be moved or jarred again until the assay is complete and ready for interpretation.
4. **Read results at 5 minutes.**

### Interpretation of Results:

#### Positive Result:

The appearance of **any pink-to-purple Test Line** next to the letter “T” in the Result Window, along with any shade of a blue Control Line next to the letter “C” indicates a positive result. A positive QuickVue Flex Strep A Test result indicates that the specimen contains group A streptococcal antigen.

**Negative Result:**

The appearance of **only** the blue Control Line next to the letter “C” in the Result Window indicates a negative result. A negative QuickVue Flex Strep A Test result indicates that the specimen is a presumptive negative for the presence of group A streptococcal antigen.

**Invalid Result:**

The test result is invalid if any shade of a blue Control Line next to the letter “C” is not visible at 5 minutes. If this occurs, retest using a new specimen and a new Test Cassette.